

Applicants: Douglas J. M. Allen et al.  
Serial No.: 10/716,098  
Filed : November 17, 2003  
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**Remarks**

Claims 12-13 and 16-26 were pending in the subject application. By this amendment, applicants have canceled claim 12, added new claims 27 and 28, and amended claims 13, 16 and 23. Applicants submit that the new claims and the amendments raise no issue of new matter. Accordingly, claims 13 and 16-28 will be pending and under examination upon entry of this response.

**Rejection under 35 U.S.C. §112, second paragraph**

In the July 12, 2007 Office Action, the Examiner rejected claims 13 under U.S.C. §112, second paragraph, alleging that there is insufficient antecedent basis for the limitation of "hydrate form" in the claim.

In response, without conceding the correctness of the Examiner's arguments or relinquishing their right to pursue patent protection for any canceled subject matter, Applicants have canceled claim 12 and amended claim 13 to be an independent claim. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

**Rejection under 35 U.S.C. §112, second paragraph**

On page 3 of the October 10, 2006 Official Action, the Examiner rejected claims 23-26, because the specification, while being enabling for a method of treating certain cancers such as breast, ovarian, colorectal prostate, and lung cancer, does not reasonably provide enablement for a method of treating all hyperproliferative disorders. The Examiner alleged that the specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. After reviewing factors including: 1) the breadth of the claims; 2) the amount of direction or guidance presented; 3) the state of the prior art; 4) the relative skill of those in the art; and 5) the predictability or unpredictability of the art, the Examiner came to the conclusion that given the unpredictable nature of the art, and the preliminary research in the art, one skilled in the art will have to carry out undue experimentation to practice the method of treatment recited in claim 23.

In response, Applicants have canceled claim 24 and amended claim 23 to recite specific disorders. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

#### **Double Patenting**

On page 6 of the July 12, 2007 Office Action, the Examiner rejected claims 12 and 16 under the "same invention" type (35 U.S.C 101) double patenting as allegedly unpatentable over claims 2 and 9 of U.S. Patent No. 6,706,721. The Examiner alleged that although the instant claim 12 does not recite the term "anhydrous form", such a form is the only form disclosed in the specification. Based on this argument, the Examiner concluded that the conflicting claims are drawn to identical subject matter.

In response, Applicants have canceled claim 12. For the record, in response to the Examiner's allegation that

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"anhydrous form" of the compound of claim 12 is the only form disclosed in the specification, applicants contend that the "hydrate form" of claim 12 is well supported in the specification. Specifically, the support for "hydrate form" of the compound of claim 12 is found, *inter alia*, in line 29-30 on page 1, line 26 on page 3, lines 21-22 on page 4, and Example 1 on page 8 of the specification.

As to the Examiner's double patenting rejection of claim 16, applicants maintain that the subject matter claimed in claim 16 is different from the invention claimed in claim 9 of the '721 patent. Specifically, subject matter claimed in claim 16 is a subset of what is claimed in claim 9 of the '721 patent. As the Examiner correctly acknowledged in the July 12, 2007 Office Action, a rejection based on double patenting of the "same invention" type, the term "same invention" means an invention drawn to identical subject matter. Because the subject matter claimed in claim 16 of the subject application is not identical to that in claim 9 of the '721 patent, a double-patenting rejection based on based on the "same invention" type is inappropriate.

Therefore, applicants respectfully request that the Examiner reconsider and withdraw the rejection of double patenting.

#### **Claim Objections**

The Examiner further objected to claims 17-22 as being dependent upon a rejected based claim. Since claim 16 is improperly rejected as explained above, applicants

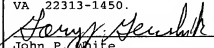
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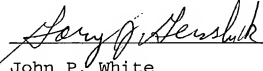
respectfully request that the Examiner reconsider and withdraw the objection to claims 17-22.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$120.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this amendment. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
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